REMARKS/ARGUMENTS

Reconsideration and allowance of the above-identified application are respectfully requested. No claims are amended herein. Claims 1-24 remain pending.

The Examiner rejected claims 15-19 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,838,887 to Idriss (hereinafter 'Idriss'). Applicants traverse the rejection since Idriss clearly fails to teach or suggest all of the elements of at least independent claim 15. First, Idriss fails to teach or suggest a restrictor channel as recited in claim 15. Idriss, by contrast, uses a valve an accumulator arrangement (see, e.g., ref. numbers 26, 28 and 30), to fill an accumulator from a reservoir and empty the reservoir into a catheter. As shown in FIG. 2B of Idriss, flow rates are determined by *how often* the valve/accumulator arrangement is operated, as opposed to metering flowrate via a restrictor channel. Second, the only resealable port shown in Idriss is in fluid communication with the *reservoir,* not the delivery cannula as recited in claim 15. The resealable port of embodiments of the present invention is provided as a means to deliver a bolus injection. Thus the resealable port is in fluid communication with the delivery cannula. In Idriss, as shown in FIG. 2B, bolus deliveries are handled by operating the valve/accumulator arrangement more often. Accordingly, since Idriss fails to teach or suggest each and every feature of claim 15, the rejection of claim 15, and claims 16-19 which depend from claim 15, must be withdrawn. Reconsideration is respectfully requested.

The Examiner has rejected claims 1-20 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,715,852 to Reinicke (hereinafter 'Reinicke').

Applicants traverse the rejection since Reinicke clearly fails to teach or suggest each and every element of at least the independent claims 1, 10, and 15. Reinicke describes two pathways between a reservoir and a catheter outlet. The first pathway flows via a pump, and is the primary path by which fluid flows from the reservoir to the catheter outlet. Also included in the first pathway is a flow control unit 42, which restricts the *maximum* flow rate in the event of a valve leak, or the like. The second pathway flows via flow control unit 48 and flow control unit 42, from the reservoir to the catheter outlet, bypassing the pump unit. The purpose of the second pathway is to guarantee a *minimum* flowrate of fluid in the event of a pump failure or a clog, or the like.

With regard to claim 1, Reinicke fails to teach or suggest a rate selector channel comprising a plurality of series-connected sections *separated by nodes*, each node being in fluid communication with a corresponding section of a primary restrictor channel *and capable of being closed.* In other words, Reinicke does not teach or suggest any way of forcing fluid through a variable number of series-connected sections of a rate selector channel by closing some number of *nodes.* In fact, Reinicke does not appear to include any structure that could be considered a *node that is capable of being closed*, as used herein. Similarly, claim 10 is directed to a method of injecting medication comprising: providing elements including a rate selector channel comprising a plurality of series-connected section separated by nodes, each node being in fluid communication with a section of a primary restrictor channel, each of said nodes being constructed such that when said node is in a closed position, fluid is not able to flow through said node from said primary restrictor channel to said rate selector channel; and *closing a selected number of nodes.* As discussed above,

Reinicke fails to teach or suggest closable nodes separating series-connected sections of a rate selector channel, and accordingly, Reinicke fails to teach or suggest a device capable of a selected number of nodes closed in order to determine the flow rate. Accordingly, claim 10, and claims 11-14 which depend therefrom, should be allowed for at least the reasons discussed above.

Reinicke, like Idriss, only provides a resealable port that is in fluid communication with the reservoir. The resealable port of Reinicke is not in fluid communication with the delivery cannula, as required by claim 15. Accordingly, claim 15, and claims 16-20 which depend therefrom, are allowable over Reinicke for at least this reason.

The Examiner rejected claims 22-24 under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 4,548,607 to Harris (hereinafter 'Harris'). Applicants traverse the rejection since Harris clearly fails to teach or suggest each and every element of at least independent claim 22. Harris is directed to a manually activated fluid delivery pump. Harris provides multiple buttons (20, 21) and a system of fluid pathways and check valves, that are *in series*, and that must be actuated in the proper order. This is to ensure that fluid is not accidentally delivered to the patient by an inadvertent press of a single button. However, claim 22 requires two parallel channels between the reservoir and the delivery cannula. The first is a restrictor channel provided between the reservoir and the delivery cannula. The second is the bolus mechanism comprising a bolus restrictor channel provided between the reservoir and a bolus button, and a bolus exit channel provided between the bolus button and the delivery cannula. The restrictor channel provides a basal fluid delivery

rate. The bolus channel provides for bolus injections, and the purpose of the bolus restrictor channel is to restrict the *refill* of the bolus button to prevent a patient from using bolus injections too frequently. Harris, by contrast, does not provide parallel channels for basal and bolus delivery, but instead describes a *single series connection* of buttons, flow channels and check valves. Accordingly, the rejection of Harris must be withdrawn for at least this reason, and claims 22-24 should be allowed.

The Examiner rejects claims 1-24 under 35 U.S.C. §103(a) as being obvious over the combination of U.S. Patent No. 5,445,616 to Kratoska (hereinafter 'Kratoska'), U.S. Patent No. 5,009,251 to Pike (hereinafter 'Pike'), and previously cited Harris. Applicants traverse the rejection since the combination of Kratoska, Pike and Harris fail to teach or suggest each and every element of at least independent claims 1, 10, 15 and 22. Kratoska merely describes a device comprising a reservoir and refillable port that are more compact because the reservoir and fill-port are not stacked on top of one another. With regard to the resealable port of claim 15, Kratoska suffers the same deficiency as the other cited references. That is, the resealable port of Kratoska is connected to the reservoir, and is for the purpose of refilling the reservoir, and is not connected in fluid communication with the deliver cannula, as required in claim 15.

With regard to independent claims 1 and 10, Pike is cited as teaching a fluid regulator that comprises "many channels and the channels have a plurality of sections and a plurality of nodes" as well as a "selectable knob, which determines the rate of fluid control by closing fluid channels throughout the device." Pike, however, fails to teach or suggest the arrangement of parallel channels and nodes as recited in at least

independent claims 1 and 10. Claims 1 and 10 both require *two* channels, a primary restrictor channel and a rate selector channel. The rate selector channel comprises a plurality of series-connected sections separate by nodes, each node being in fluid communication with a corresponding section of said primary restrictor channel, and capable of being closed, such that when a particular node is closed, fluid flowing from the reservoir toward the cannula may not pass through the node but rather must pass through the corresponding section of the primary restrictor channel. Pike, by contrast, merely describes a long *single* channel with various nodes that are *normally closed.* One of the nodes can be opened by the selector knob, thus determining the effective length of the channel. Pike does not describe a parallel channel, and hence cannot describe nodes that connect sections of a primary restrictor channel with sections of a rate selector channel. Kratoska and Harris fail to make up for this deficiency. Accordingly, the rejection of claims 1 and 10, and also claims 2-9 and 11-14 which depend therefrom, respectively, should be allowed.

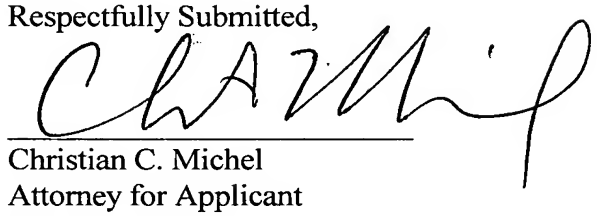
Since each of the cited references, Kratoska, Pike and Harris teach only a single pathway from reservoir to outlet, none of them can possibly describe the parallel channels recited in claim 22 (primary restrictor channel, and bolus channel). For at least this reason, the rejection of claim 22, and hence claims 23 and 24 which depend therefrom, must be withdrawn.

Separately, claims 3 and 21 require the primary restrictor channel to be formed in a serpentine pattern. None of the references teach or suggest this feature, so claims 3 and 21 should be allowed for at least this additional reason.

The Examiner rejected claims 1-24 on the ground of nonstatutory obviousness-type double patenting over U.S. Patent No. 6,702,779. Applicants submit herewith a terminal disclaimer to overcome the rejection.

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully Submitted,



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